

Notice of Allowability**Application No.**

10/031,401

Applicant(s)

WILHELM ET AL.

Examiner

Jennifer I. Harle

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 7/12/04.
2. ☒ The allowed claim(s) is/are 4-7.
3. ☒ The drawings filed on 18 January 2002 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 10/04/2004 .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

Claims 1-7 were pending. Claims 8-13 would have been withdrawn as non-elected. However, claims 4-7 are allowed and claims 1-3 and 8-13 are canceled by Examiner's Amendment with authorization by Applicants' counsel.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

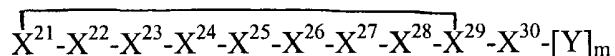
Authorization for this examiner's amendment was given in a telephone interview with Patrick Skacel, Applicants' Representative on October 4, 2004. The application has been amended as follows:

Claim 1. (Canceled).

Claim 2. (Canceled).

Claim 3. (Canceled).

Claim 4. (Original Claim) A compound of the general structural formula (I):



wherein $X^{21}-X^{30}$ are monomeric building blocks, preferably aminocarboxylic acid residues and are derived from a structure in which X^{21} = D-Cys, X^{22} = Asn, X^{23} = Dap, Dab, or Nle, X^{24} = Tyr, X^{25} = Phe, X^{26} = Ser, X^{27} = Asn, X^{28} = Ile, X^{29} = Cys and X^{30} = Trp, Y is a spacer and m is 0 or 1, and the monomeric building blocks are linked via $-\text{CONR}^1$ or $-\text{NR}^1\text{CO}$

Art Unit: 1654

bonds, in which R^1 in each case independently is hydrogen, methyl or ethyl, and pharmaceutically acceptable salts and derivatives thereof.

Claim 5. (Twice Amended) The compound as claimed in claim 4, characterized in that at least 2 of the amino acid residues X^{22} , X^{23} , X^{24} , X^{25} , X^{26} , X^{27} , X^{28} and X^{30} have the same side chain as an amino acid at the same position in the native UPA sequence.

Claim 6. (Original Claim) The compound as claimed in claim 5, characterized in that at least 2 of the amino acid residues X^{24} , X^{25} , X^{28} and X^{30} have the same side chain as in the native UPA sequence.

Claim 7. (Twice Amended) A pharmaceutical composition, which contains as active substance at least one compound as claimed in claim 4, where appropriate together with pharmaceutically common ~~carriers~~ carriers, excipients or diluents.

Claim 8. (Canceled).

Claim 9. (Canceled).

Claim 10. (Canceled).

Claim 11. (Canceled).

Claim 12. (Canceled).

Claim 13. (Canceled).

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: none of the prior art teaches or suggests a cyclic peptide of the general structure claimed in formula I of claim 4 where the substitution at position X^{23} is Dap, Dab or Nle.

Art Unit: 1654

The closest prior art was previously cited to break unity and is WO 98/46632 and does not teach or suggest any substitution at X²³ is Dap, Dab or Nle.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer I. Harle whose telephone number is (571) 272-2763. The examiner can normally be reached on Monday through Thursday, 6:30 am to 5:00 pm,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jennifer Ione Harle
October 4, 2004



CHRISTOPHER R. TATE
PRIMARY EXAMINER